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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/822,585 | 03/30/2001 | Lino R. Becerra | MGH-004BUS | 1273 |

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EXAMINER

SHAW, SHAWNA JEANNINE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3737

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/822,585

Applicant(s)

BECERRA ET AL.

Examiner

Shawna Shaw

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 31-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7-9,11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election of Group I in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. The drawings are objected to because element 79 is not shown in figure 2C and elements 100 and 118 are not shown in figure 3. Also, the "?" in figure 11D should be replaced with appropriate text. Moreover, it appears that figures 7A, 7G, 8A, 8C, 10C and 14A for example, should be color drawings. See corresponding discussions of these figures in the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first

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paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Information Disclosure Statement

4. The articles in the information disclosure statement filed 9/20/01 have been inadvertently misplaced. In order for the references to be considered, applicant is required to submit a copy of all articles cited in this communication in response to this office action.

Claim Objections

5. Claims 5-7, 18 and 30 are objected to because of the following informalities: In claim 5, the full name of all the regions should be provided. For example, "S1" should be --primary somasensatory cortex (S1)--, etc. In claim 7, the full name of all the neuroimaging devices should be provided. For example, "fMRI" should be --functional magnetic resonance imaging (fMRI)--, etc. Claim 18 should provide the full name of "an R index" and "an L index." Claim 30 is missing its numeral designation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear from the specification *how* the waveform based correction analysis (WCA) temporally segregates the mean hemodynamic response (as depicted by reference numeral 914) into early and late phases/phase components (as depicted by reference numerals 918 and 920). See p. 88 line 22 – p. 89 line 5 of the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn toward a method for measuring brain activity, however no measuring step has been set forth. In claim 1, the correlating step is incomplete in that it is unclear what the signals in a brain region are being correlated with. In claim 26, element designations "(a)", "(b)" and "(c)" conflict with those in claim 23. In claim 29, "the treatment" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-7, 9, 10, 19, 20 and 22-30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Breiter et al. "Acute Effects of Cocaine on Human Brain Activity and Emotion" of record.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breiter et al. "Acute Effects of Cocaine on Human Brain Activity and Emotion" of record.

Regarding claims 4 and 8, Breiter et al. does not specifically address the trigeminal nucleus, however absent any showing of criticality, the body region imaged would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made depending upon the particulars of the activity being measured.

Regarding claim 21, Breiter et al. differs from the claimed invention in that a neural network is not specifically addressed, however absent any showing of criticality, the type of processor used would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made depending upon the particulars of the application.

10. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breiter et al. "Acute Effects of Cocaine on Human Brain Activity and Emotion" of record in view of Hu et al.

Regarding claims 11-18, Breiter et al. teaches temporally segregating central nervous system activity into early and late phases, however differs from the claimed invention in that statistical analysis techniques are used instead of waveform based correction analysis (WCA). Hu et al. provides the general teaching of generating functional activation maps by correlating image data with hemodynamic response data. See e.g., col. 13 lines 1-14. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use a waveform based correction analysis technique as taught by Hu et al. in the invention as taught by Breiter et al. to provide

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improved sensitivity to signal changes arising from small vessels associated with the spatial origin of neuronal activation.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Shawna J. Shaw
Primary Examiner
February 11, 2003